

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:

**Enrofloxacin for Poultry:  
Withdrawal of Approval of  
New Animal Drug Application  
NADA 140-828**

**FDA DOCKET: 00N-1571**

**RESPONDENT BAYER CORPORATION'S FIRST  
REQUEST FOR PRODUCTION OF DOCUMENTS TO CVM**

Pursuant to Administrative Law Judge Davidson's April 10, 2002 Order and the parties' June 6, 2002 agreement, Respondent Bayer propounds these Requests for Production of Documents, to which CVM shall respond separately and fully on or before July 24, 2002, in accordance with the Instructions and Definitions set forth hereinafter.

**INSTRUCTIONS**

1. If, in responding to this Request for Production, the responding party encounters any ambiguities when construing a request or definition, the response shall set forth the matter deemed ambiguous and the construction used in responding.
2. Whenever in this Request you are asked to identify or produce a document which is deemed by you to be properly withheld from production for inspection or copying:
  - A. If you are withholding the document under claim of privilege (including, but not limited to, the work product doctrine), please provide information, including the type of document, the general subject matter of the document, the date of the document, and such other information as is sufficient to identify the document, including, where appropriate, the author, addressee, custodian, and any other recipient of the document, and where not apparent, the relationship of the author, addressee, custodian, and any other recipient to each other, in a manner that, without revealing the information claimed to be protected, will enable this party to assess the applicability of the privilege or protection claimed by you;
  - B. If you are withholding the document for any reason other than an objection that it is beyond the scope of discovery or that a request is unduly burdensome, identify as

to each document **and**, in addition to the information requested in 2.A, above, please state the reason for withholding the document.

3. When a document contains both privileged and non-privileged material, the non-privileged material must be disclosed to the fullest **extent** possible without thereby disclosing the privileged material. If a privilege is **asserted** with regard to part of the material contained in a document, the party claiming the privilege must clearly indicate the portions as to which the privilege is claimed. **When a document has been redacted** or altered in any fashion, identify as to each document the reason for the redaction or alteration, the date of the redaction or alteration, and the person performing the redaction or alteration. Any redaction must be clearly visible on the redacted document.
4. It is intended **that** these Requests will not solicit any material protected either by the attorney/client privilege or by the work product doctrine which was created by, or developed by, counsel for the responding party after the date on which this **matter** was commenced. If any Request is susceptible of a construction which calls for the production of such material, that material need not be provided.
5. It is intended **that these Requests** will not solicit any material already submitted by CVM to the docket pursuant to 21 CFR §12.85.
6. If production of any requested document(s) is objected to on the grounds that production is unduly burdensome, describe the burden or expense of the proposed discovery.

## **DEFINITIONS**

Notwithstanding any definition set forth **below**, each word, term, or phrase used in this Request is intended to have the broadest **meaning** permitted. **As** used in this Request, the following terms are to be interpreted in accordance with these definitions:

1. Communication: The term "**communication**" means the transmittal of information by any means.
2. Concerning: The term "**concerning**" means relating to, referring to, describing, evidencing, or constituting.
3. Document: The terms "**document**" and "**documents**" are defined to be synonymous in meaning and equal in scope to the usage of the term "**documents**" in Fed. R. Civ. P. 34(a) and include(s) the term "**writing**". Unless the producing party demonstrates undue burden or other grounds sufficient to meet the requirements of Fed. R. Civ. P. 26(c), electronic mail is included within the definition of the term "**document**". The terms "**writings**", "**recordings**", and "**photographs**" are defined to be synonymous in meaning and equal in scope to the usage of those terms in Fed. R. Evid. 1001. A draft or non-identical copy is a separate document within the meaning of the term "**document**".

4. Parties: The term "CVM" shall **mean** the FDA Center for Veterinary Medicine and any person working on its behalf in this matter.
5. Person: The term "person" is defined **as** any natural person or any business, legal or governmental entity, or association.
6. You/Your: The terms "you" or "your" include the person(s) to whom this Request is addressed, and all of that person's agents, representatives and attorneys.
7. The present tense includes the past and future tenses. The singular includes the plural, and the plural includes the singular. "All" means "any and all"; "**any**" means "any and all." "Including" means "including but not limited to." "**And**" and "or" encompass both "and" and "or." Words in the masculine, feminine or neuter form shall include each of the other genders.
8. If the requested documents are maintained in a file, the file folder is included in the request for production of those documents.

#### **REQUESTS FOR PRODUCTION'**

1. All documents referred to in your Answers to Interrogatories.
2. All statements made by CVM and any of its present or former directors, officers, or employees, concerning: whether enrofloxacin use in poultry acts as a selection pressure, resulting in the emergence and dissemination of **fluoroquinolone-resistant *Campylobacter* spp.** in poultry; whether **fluoroquinolone-resistant *Campylobacter* spp.** in poultry are transferred to humans and contribute to **fluoroquinolone-resistant *Campylobacter*** infections in humans; and whether **fluoroquinolone-resistant *Campylobacter*** infections in humans have the potential to adversely effect human health.
3. All documents concerning pre-1996 levels of **fluoroquinolone-resistant *Campylobacter*** in humans in the United States.
4. All documents concerning pre-1996 levels of **fluoroquinolone-resistant *Campylobacter*** in poultry in the United States.
5. All documents (**including, but not limited to, correspondence, notes, memoranda, and journal entries**) which relate to, describe, summarize, or memorialize any communication between CVM and any employee of CDC concerning NARMS quinolone resistance rates for human ***Campylobacter*** isolates from 1992 to present.
6. All documents (**including, but not limited to, correspondence, notes, memoranda, and journal entries**) which relate to, describe, summarize, or memorialize any

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<sup>1</sup> Again, per instruction #5, it is intended that these Requests will not solicit any material already submitted by CVM to the docket pursuant to 21 CFR § 12.85.

communication between CVM and any employee of CDC concerning the validity of NARMS, establishing of the NARMS protocol, uses of NARMS generated data and use of NARMS data for regulatory purposes.

7. All documents (including, but not limited to, correspondence, notes, memoranda, and journal entries) which relate to, describe, summarize, or memorialize any communication between CVM and any employee of USDA concerning NARMS quinolone resistance rates for poultry *Campylobacter* isolates from 1992 to present.
8. All documents (including, but not limited to, correspondence, notes, memoranda, and journal entries) which relate to, describe, summarize, or memorialize any communication between CVM and any employee of USDA concerning the validity of NARMS, establishing of the NARMS protocol, uses of NARMS generated data and use of NARMS data for regulatory purposes.
9. All documents (including, but not limited to, correspondence, notes, memoranda, and journal entries) which relate to, describe, summarize, or memorialize any communication between CVM and any employee of the Minnesota Department of Health concerning human *Campylobacter* isolates from Minnesota from 1992 to present, including but not limited to communications concerning quinolone resistance levels.
10. All documents (including, but not limited to, correspondence, notes, memoranda, and journal entries) which relate to, describe, summarize, or memorialize any communication between CVM and any employee of the Connecticut Department of Health concerning human *Campylobacter* isolates from Connecticut from 1992 to present, including but not limited to communications concerning quinolone resistance levels.
11. All documents (including, but not limited to, correspondence, notes, memoranda, and journal entries) which relate to, describe, summarize, or memorialize any communication between CVM and any employee of the Georgia Department of Health concerning human *Campylobacter* isolates from Georgia from 1992 to present, including but not limited to communications concerning quinolone resistance levels.
12. All documents (including, but not limited to, correspondence, notes, memoranda, and journal entries) which relate to, describe, summarize, or memorialize any communication between CVM and any employee of any NARMS FoodNet site concerning human *Campylobacter* isolates from Georgia from 1992 to present, including but not limited to communications concerning quinolone resistance levels.
13. All documents concerning any consultations a/k/a "consults" received from CDER, and/or the anti-infective statistics group and/or epidemiology statistics group on the issue of antibiotic resistance caused by the use of fluoroquinolones in poultry.

14. All documents relating to correspondence, instructions, minutes of meetings, other background materials, and contracts or agreements entered into between FDA or CVM and David Vose concerning performance of the CVM risk assessment "Human Health Impact of Fluoroquinolone-Resistant *Campylobacter* Attributed to the Consumption of Chicken" October 18, 2000.
15. Any correspondence or other response from FDA Commissioner David A. Kessler, MD, or anyone acting on his behalf, to CDC Director David Satcher's August 16, 1995 letter regarding (among other issues) use of fluoroquinolones in animals (G-559).
16. February 20, 1996 letter from Joe S. Gloyd of AVMA to CVM as referenced in G-1003.
17. All documents (including, but not limited to, correspondence, notes, memoranda, and journal entries) which relate to, describe, summarize, or memorialize Ciprofloxacin susceptibility test results (i.e., MIC or E-test results) for all *Campylobacter* isolates from the FoodNet surveillance data base for year 2001
18. All documents including any raw data or correspondence relating to the sentinel county survey conducted in selected counties in 1989-1990, where "331 *Campylobacter* isolates were isolated from patients with diarrhea and submitted to CDC for antimicrobial susceptibility testing." As reported in "Update: National Antimicrobial Resistance Monitoring System (NARMS) activities pertaining to fluoroquinolone resistance" (G-95).
19. All documents, including any raw data or correspondence from CDC, related to the sentinel county survey as reported in the abstract entitled "The Burden of *Campylobacter jejuni* Infections: A Target for Early Treatment?" by Sobel J., Tauxe R., et al. (G-592).

Respectfully submitted,



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**CERTIFICATE OF SERVICE**

I hereby certify that a copy of Respondent Bayer's First Request for Production of Documents to CVM was sent via e-mail and mailed this 24th day of June 2002, via first-class mail, postage pre-paid to:

Nadine R. Steinberg, Esquire  
Food and Drug Administration  
Office of General Counsel (CGF-1)  
5600 Fischers Lane, Room 7-77  
Rockville, MD 20857


Kent D. McClure  
Animal Health Institute  
1325 G Street, N.W., Suite 700  
Washington, D.C. 20005

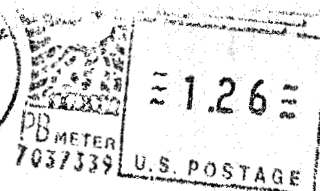
and was sent via facsimile and mailed this 24th day of June 2002, via first-class mail, postage pre-paid to:

Honorable Daniel J. Davidson  
Administrative Law Judge  
Food and Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, Maryland 20857

and was mailed this 24th day of June 2002, via first-class mail, postage pre-paid to:

Dockets Management Branch (HFA - 305) - FDA  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20857

  
Robert B. Nicholas



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